Image RCE/1654

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) **$385.00**

Complete if Known	
Application Number	09/876,304
Filing Date	June 7, 2001
First Named Inventor	Isiah M. Warner
Examiner Name	Audet, M.
Art Unit	1654
Attorney Docket No.	Warner 9802.2

METHOD OF PAYMENT *(check all that apply)*

☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: **20-0096**

Deposit Account Name: **Taylor Porter Brooks & Phillips**

The Director is authorized to: *(check all that apply)*

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND

	Extra Claims			Fee from below	Fee Paid
Total Claims		-20** =	0	X 9.00 =	0.00
Independent Claims		- 3** =	0	X 43.00 =	0.00
Multiple Dependent				=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) **$0.00**

**or number previously paid, if greater; For Reissues, see above*

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non - English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR § 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Statement	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	385.00
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) **$385.00**

SUBMITTED BY

Complete *(if applicable)*

Name (Print/Type)	John H. Runnels	Registration No. (Attorney/Agent)	33,451	Telephone	(225) 387-3221
Signature	John H. Runnels			Date	February 26, 2004

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This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Isiah M. Warner *et al.*

Serial No. 09/876,304

Filed: June 7, 2001

For: "Polymerized Oligopeptide-Surfactant Chiral Micelles" (Atty File 9802.2 Warner)

Group 1654

Examiner Audet, M.

REQUEST FOR CONTINUED EXAMINATION UNDER 37 C.F.R. § 1.114

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Request for Continued Examination is submitted in response to the Final Action dated December 18, 2003.

Enclosed is a check for the $385 fee for a request for continued examination (37 C.F.R. § 1.17(e)). If this amount is incorrect, please refer to the Deposit Account

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CERTIFICATE

I hereby certify that this Request for Continued Examination and the enclosed check for $385 are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 26, 2004.

John H. Runnels

John H. Runnels
Registration No. 33,451
February 26, 2004

Authorization previously filed for this application. If any extension of time is required, please consider this paper a petition for the total extension of time required.

Reexamination and reconsideration of the application are respectfully requested.

No additional amendments are presented.

Claims 18-23, and 45-53 remain in the application.

The § 112, First Paragraph Rejections

Claims 18-21 were rejected under 35 U.S.C. § 112, first paragraph as lacking a written description in the specification.

M.P.E.P. § 2163, subpart (I)(A), first paragraph clearly states: "There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." (citation omitted)

Claims 18-21 of the present divisional application are identical to Claims 18-21 of the "parent" application, S.N. 09/296,351, filed April 22, 1999. They are also identical to Claims 18-21 of the "grandparent" application, S.N. 60/126,431, filed April 29, 1998.

The Claims in question are identical to the corresponding Claims as filed in the original priority application. Not one word has been changed. Thus each of these Claims continues to be entitled to the "strong presumption" of M.P.E.P. § 2163 that an adequate written description is present. With all respect, the December 18, 2003 Office Action has not rebutted this "strong presumption."

The Applicants are entitled to rely on the strong presumption that the written description requirement is satisfied for all Claims as originally filed. Until the Office rebuts this presumption, the Applicants should have no obligation to respond further to overcome this ground of rejection.

See also M.P.E.P. § 2163, subpart (II)(A), first paragraph (citation omitted): "There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed . . . . Consequently, rejection of an original claim for lack of written description should be rare." See also M.P.E.P. § 2163.03, first paragraph. This application does not present the rare exception to the general rule.

The December 18, 2003 Office Action at page 4 acknowledged that the specification provides an adequate disclosure to support the use of any amino acids in the invention as part of the polymerized dipeptide chiral micelles.

However, the Office Action at page 4 stated that "one of skill in the art would not recognize from the disclosure that the Applicant was in possession of the micelles, namely what specific compound polymers (cl. 18-21) are contemplated to work in the invention."

Thus, if the Applicants have correctly understood this ground of rejection, then the primary issue appears to be whether the specification contains an adequate written description of the class of polymerized micelles generally. Applicants respectfully submit that the specification amply describes polymerized micelles generally, and that the written description rejection should therefore be withdrawn.

The disclosure of a patent specification is, of course, directed not to the layperson but to a person of ordinary skill in the art. That which is known to those of skill in the art need not be disclosed. It is well-settled that a patent specification need not be, and should not be, a catalog of existing technology. A patent specification need not disclose, and preferably omits, what is already well known in the art. See M.P.E.P. § 2164.05(a), sixth paragraph. See also M.P.E.P. § 2163, subpart (II)(A)(2), first paragraph (citation omitted): "Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of the disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification."

See also § 2163, subpart (II)(A)(3)(a), seventh paragraph (citations omitted): "What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met."

M.P.E.P. § 2163, subpart (I)(A), first paragraph explains that a question of written description may arise for claims as originally filed "if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art."

By contrast, the present specification on its face fully describes polymerized micelles. Furthermore, many aspects of the claimed polymerized micelles rely on information that is already known in the art. Finally, the specification gives guidance as to where in the art further pertinent information may be found. Thus the written description requirement is more than satisfied.

It should require no citation that, long before the 1998 priority date of the present application, it was notoriously well-known in the chemical arts how to make micelles from surfactant molecules.

It should also require no citation that it was notoriously well-known in the chemical artsgenerally how to polymerize monomer molecules containing polymerizable functionalities.

Also known in the chemical arts was how to combine these two principles, i.e., how to make polymerized micelles from surfactant molecules containing polymerizable functionalities.

A patent specification need not be burdened by, its length need not be multiplied excessively by, the unnecessary inclusion of detailed information concerning matters that were well known in the art. The present specification provides more than ample guidance on each of these points. Below are some excerpts from the specification. Note that, in addition to the detailed guidance that is given directly in the specification, there are also numerous citations to outside references to supply further guidance. Such citations are a well-accepted means to supplement a patent disclosure, without unduly lengthening the specification with material that is already known in the art, as discussed below concerning the incorporations by reference. Also note that several specific examples are given.

Micelles

> Surfactants, molecules having both hydrophilic and hydrophobic groups, associate with one another in polar solvents such as water to form dynamic aggregates known as "micelles." A micelle typically takes roughly the shape of a sphere, a spheroid, an ellipsoid, or a rod, with the hydrophilic groups on the exterior and the hydrophobic groups on the interior. The

hydrophobic interior provides, in effect, a hydrophobic liquid phase with solvation properties differing from those of the surrounding solvent. Micelles form when the concentration of the amphophilic molecules in solution is greater than a characteristic value known as the critical micelle concentration ("**CMC**").

Micelles have been used for a variety of purposes, including micellar catalysis; micelle-substrate interactions; and analytical applications such as spectroscopic analyses, electrochemical measurements, and separations. For example, K. Taguchi *et al.*, "Immobilized Bilayer Stationary Phases in Gas Chromatography," J. Chem. Soc., Chem. Commun., pp. 364-365 (1986) disclose the use of an immobilized, stable, poly-ion complex containing vesicles for use in a gas chromatography column.

For a general discussion of micellar electrokinetic capillary chromatography, see S. Terabe *et al.*, "Electrokinetic Chromatography with Micellar Solution and Open-Tubular Capillary," Anal. Chem., vol. 57, pp. 834-841 (1985); and S. Terabe *et al.*, "Electrokinetic Separations with Micellar Solutions and Open-Tubular Capillaries," Anal. Chem., vol. 56, pp. 111-113 (1984).

Chiral Micelles

An important application of micelles is their use in chiral recognition and separation. Chiral surfactants have been used to form micelles having distinct chiral properties. The resulting chiral microenvironment has been shown to exhibit selective interactions with different enantiomers in solution. See, e.g., S. Terabe *et al.*, "Chiral Separation by Electrokinetic Chromatography with Bile Salt Micelles," J. Chromatog., vol. 480, pp. 403-411 (1989); S. Terabe *et al.*, "Separation of Enantiomers by Capillary Electrophoretic Techniques," J. Chromatog. A, vol. 666, pp. 295-319 (1994); T. Ward, "Chiral Media for Capillary Electrophoresis," Anal. Chem., vol. 66, pp. 632A-640A (1994); and M. Novotny *et al.*, "Chiral Separation through Capillary Electromigration Methods," Anal. Chem., vol. 66, pp. 646A-655A (1994).

In addition to the equilibrium between micelles and ligands, there is also a dynamic equilibrium between surfactant molecules and micelles. "Conventional" micelles are dynamic aggregates of surfactant monomers; the monomers exist in equilibrium between aggregation in micelles, and being free in solution as smaller aggregates down to monomers. Because the difference in interactions between a chiral micelle and two enantiomers is often very small, these dynamic equilibria may interfere with the separation of enantiomers. See the schematic diagram of Figure 1(a), in which an asterisk represents a chiral center, and S represents the solute.

Mixed chiral micelle systems have been reported to have enhanced resolving power as compared to the resolving power of micelles formed from the individual components. See K. Otsuka *et al.*, "Enantiomeric Resolution by Micellar Electrokinetic Chromatography with Chiral Surfactants," J. Chromatog., vol. 515, pp. 221-226 (1990); and Y. Ishihama *et al.*, "Enantiomeric Separation by Micellar Electrokinetic Chromatography Using Saponins," J. Liq. Chromatog., vol. 16, pp. 933-944 (1993).

Polymerized Micelles

Polymerized surfactant aggregates, or polymerized micelles, were first developed in the late 1970's and early 1980's. Compared to otherwise identical non-polymerized micelles ("conventional micelles"), polymerized micelles exhibit enhanced stability, enhanced rigidity, and better control over micelle size. The covalent bonds between surfactant monomers essentially eliminate the dynamic equilibrium between surfactant monomers and "conventional" micelles, simplifying and enhancing complexation between micelle and ligand.

An important advantage of polymerized micelles is that they have no critical micelle concentration ("**CMC**"). Because the individual surfactant monomers in a polymerized micelle must associate with one other, micelles form regardless of how low their concentration is. By contrast, with non-polymerized micelles the concentration of the surfactant must be higher than the CMC for a significant concentration of micelles to form. Furthermore, if the CMC of a charged surfactant is high, the high concentration of surfactant will generate considerable heat in micellar electrokinetic capillary chromatography (MECC), due to the high current resulting from the high charge density in solution. The heat generated can be deleterious to separations. By contrast, generation of heat with polymerized micelles can be greatly reduced because polymerized micelles have no CMC.

C. Palmer *et al.*, "A Monomolecular Pseudostationary Phase for Micellar Electrokinetic Capillary Chromatography," J. High Res. Chromatog., vol. 15, pp. 756-762 (1992) discloses the use of an oligomerized sodium 10-undecylate micelle-like structure in micellar electrokinetic capillary chromatography. See also C. Larrabee *et al.*, "Radiation-Induced Polymerization of Sodium 10-Undecenoate in Aqueous Micelle Solutions," J. Poly. Sci.: Poly. Lett. Ed., vol. 17, pp. 749-751 (1979).

Polymerized micelles are typically more rigid than conventional micelles, a property that may result in faster mass transfer. Polymerized micelles have a more compact structure than do conventional micelles. Thus solute molecules do not penetrate as deeply, which may result in faster mass transfer rates. See C. Paleos *et al.*, "Comparative Studies between

Monomeric and Polymeric Sodium 10-Undecenoate Micelles," J. Phys. Chem., vol. 87, pp. 251-254 (1983).

For other disclosures of polymerized micelles and their uses in separations, see also D. Tabor *et al.*, "Some Factors in Solute Partitioning between Water and Micelles or Polymeric Micelle Analogues," Chromatog., vol. 20, pp. 73-80 (1989); S. Terabe *et al.*, "Ion-Exchange Electrokinetic Chromatography with Polymer Ions for the Separation of Isomeric Ions Having Identical Electrophoretic Mobilities," Anal. Chem., vol. 62, pp. 650-652 (1990); J. Fendler *et al.*, "Polymerized Surfactant Aggregates: Characterization and Utilization," Acc. Chem. Res., vol. 17, pp. 3-8 (1984); and C. Palmer *et al.*, "A Monomolecular Pseudostationary Phase for Micellar Electrokinetic Capillary Chromatography," J. High Res. Chromatog., vol. 15, pp. 756-762 (1992).

Polymerized Chiral Micelles

Polymerized chiral micelles eliminate much of the complex dynamic behavior otherwise associated with micelles. Polymerized chiral micelles often have stronger chiral recognition properties than do otherwise-identical, "conventional" or non-polymerized chiral micelles.

In addition, recovery of chiral ligands from polymerized chiral micelles is often easier; the chiral ligands may typically be recovered by simple extraction with an appropriate organic solvent. By contrast, recovering the solute from a conventional, non-polymerized micellar medium by extraction with an organic solvent frequently causes the formation of troublesome emulsion systems. Polymerized chiral micelle systems are therefore beneficial in both preparative-scale and process-scale separations.

Enantiomeric separations employing polymerized chiral surfactants are disclosed in Wang, J.; Warner, I. M. *Anal. Chem.* 1994, 66, 3773-3776; Dobashi, A.; Hamada, M.; Dobashi, Y. *Anal. Chem.* 1995, 67, 3011-3017; and Wang, J.; Warner, I. M. *J. Chromatog.* 1995, 711, 297-304. See also commonly-assigned United States patent application serial number 08/698,351, now allowed with the issue fee paid; and Japanese patent applications 04149205 (May 1992) and 04149206 (May 1992).

Specification, page 3, line 14 through page 6, line 8.

* * * *

Dipeptide chiral micelle polymers in accordance with the present invention may be used as mobile phase additives for chiral separations in

capillary electrophoresis, or in micellar liquid chromatography under reversed phase conditions. Our method of preparing chiral micelle polymers is easy to implement, and readily lends itself to use with a variety of polymers having different structures and degrees of chirality, which can be manipulated to enhance the chiral separations for particular analytes. Using synthetic means known in the art, the chiral centers can be moved to different locations along the individual monomers, and the number of chiral centers per micelle can be increased or decreased by using micelles with higher or lower aggregation numbers, respectively. Different monomer lengths may readily be generated through means known in the art. Fatty acid-type monomers terminating in double bonds are preferred, because such monomers may be used in the synthetic scheme described above with minimal modifications to the synthesis.

Specification, page 33, lines 9-19.

* * * *

The synthetic scheme outlined above is a fairly general one in which the final steps may be modified to obtain a surfactant monomer with a different chiral center. For example, if π-π interaction is desired at the chiral center, phenylalanine, tyrosine, or tryptophan could be used in place of valine in the monomer synthesis. Histidine could also be used where a π-π interaction is desired, with care taken to "protect" one of the two amino groups of the histidine ring during synthesis.

In general, any unsaturated fatty acid may be substituted for undecylenic acid to serve as the "backbone" for the chiral monomer. Examples of naturally-occurring, readily available unsaturated fatty acids include palmitoleic acid, oleic acid, linoleic acid, linolenic acid, arachidonic acid, caproleic acid, elaidic acid, brassidic acid, erucic acid, nervonic acid, and vaccenic acid. The chemistry of attaching the chiral group to these unsaturated fatty acids, and their polymerization into chiral micelle polymers, will be essentially similar to that described above. Although preferred, the "backbone" of the monomer need not be a fatty acid or fatty acid derivative. Other amphophilic molecules could also be used for the "backbone," using methods known in the art of organic synthesis for attaching chiral groups to the backbone, and for polymerizing the chiral surfactant monomers into micelle polymers.

An example of the present invention is a polymerized dipeptide chiral micelle, wherein said polymerized dipeptide chiral micelle is not a polymer of a compound selected from the group consisting of *N*-undec-10'-enoyl-L-

prolyl-L-glutamic acid, *N*-undec-10'-enoyl-L-methionyl-L-glutamic acid, and *N*-undec-10'-enoyl-L-phenylalanyl-β-alanine. Another example of the present invention is polymerized dipeptide chiral micelle as just described, wherein said micelle comprises a polymer of monomers, wherein each of said monomers comprises an unsaturated hydrocarbon chain linked to a chiral dipeptide.

Various amino acids can be substituted for valine to synthesize other surfactant monomers analogous to L-SUVV, surfactant monomers that can then be polymerized to form other micelle polymers. Any amino acids may be used as the chiral groups, including alanine, valine, leucine, isoleucine, proline, tryptophan, phenylalanine, methionine, glycine, serine, threonine, tyrosine, cysteine, glutamine, asparagine, lysine, arginine, histidine, aspartic acid, glutamic acid, and modified amino acids.

Specification, page 34, lines 1-19 (as amended).

The specification provides ample direct guidance in the preparation of polymerized chiral micelles in accordance with the present invention. Furthermore, as is readily apparent from even a cursory review of the passages cited above, numerous outside documents were cited as well, references where additional information may be located if desired. Each of these documents was expressly incorporated into the disclosure by reference. See the specification at page 36, lines 26-27. Incorporations by reference are a well-accepted means to supplement the disclosure without unduly lengthening the specification with material that is already known in the art. "The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed." M.P.E.P. § 2163.07(b). See also M.P.E.P. § 608.01(p), subpart (I).

(For the record, it is Applicants' belief that no "essential material" has in fact been incorporated by reference, as that term is used in M.P.E.P. § 608.01(p). Because the disclosure provides ample direct guidance, and because a patent specification need not disclose that which is already known to those of skill in the art, it is believed that the specification on its face more than satisfies the written description requirement. However, the incorporations by reference provide a useful fall-back position, to provide for the possibility that something significant might have been inadvertently overlooked, or to

provide for the possibility that the Office might find something to be "essential material" that the Applicants had not expected when the specification was originally drafted and filed.)

Some Remarks Concerning Issued Patent 6,270,640

The "parent" application has now issued as U.S. Patent 6,270,640. The limitations to which the Office has objected in the present application generally have one or more counterparts in the limitations of the issued claims of the '640 patent. See, e.g., Claims 1, 11, 12, and 13 of the '640 patent. (Applicants are not suggesting that the claim scope is identical, but rather that the limitations in question generally have counterpart limitations in the issued claims.)

The Office has previously determined that the Claims of the '640 patent are patentable, which means among other things that each of those Claims is supported by an adequate written description. By analogy, it should follow that the limitations at issue in the present application are also supported by an adequate written description.

Written description summary

It is respectfully submitted that the written description rejection should be withdrawn.

Miscellaneous: Claims 23, and 45-53

For the reasons given above, it is respectfully submitted that all Claims should now be allowed.

Strictly in the alternative, Applicants note that the December 18, 2003 office action entered no grounds of rejection or objection against any of Claims 45-53. Thus, even if the Office should disagree with Applicants' other arguments, it is respectfully submitted that the Office should nevertheless allow at least Claims 45-53.

Likewise, the Office's stated grounds for rejecting independent Claim 18 do not appear to apply to dependent Claim 23. The limitations added by dependent Claim 23 appear to overcome the grounds given by the Office for rejecting independent Claim 18. Thus, in the alternative, even if the Office should repeat the rejection of Claim 18, it is respectfully submitted that Claim 23 should be acknowledged as being directed to

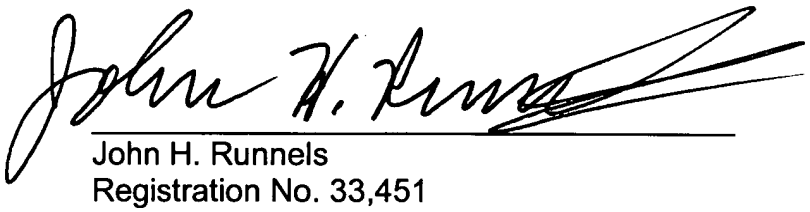
patentable subject matter. In such a case, Claim 23 might be objected to, but the Office should acknowledge Claim 23 to be allowable if re-written in independent form.

It is repeated that these observations concerning Claims 23 and 45-53 are made strictly in the alternative, and that for the reasons previously given all Claims should be allowed.

Conclusion

Allowance of Claims 18-23, and 45-53 at an early date is respectfully requested.

Respectfully submitted,



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February 26, 2004